



Trinity Health | Saint Mary's
Of New England | Hospital

Accepted
7/17/18
SHN

Office of the President
Steven E. Schneider, MD, MBA

July 10, 2018

Susan Newton, R.N.
Supervising Nurse Consultant
Facility Licensing and Investigations Section
410 Capitol Avenue
MSH #12HSR
PO Box 340308
Hartford, CT 06134

Dear Ms. Newton:

Enclosed is the Plan of Correction we have developed for violations of the Regulations of Connecticut State Agencies and/or General Statutes of Connecticut which were noted during the course of unannounced visits at Saint Mary's Hospital concluding on May 3rd by a representative of the Facility Licensing and Investigation Section of the Department of Public Health.

The Plan of Correction reflects the measures to prevent a recurrence of the identified violations, the effective date in which compliance will be achieved and the identity of the staff members by role who are responsible for monitoring the Plan of Correction as required.

If you have additional questions, please feel free to contact Lisa Fucci at 203-709-3682.

Respectfully,

Steven E. Schneider, MD, MBA
President

Enclosure

STATEMENT OF VIOLATIONS			Date of Inspection:
Saint Mary's Hospital	56 Franklin Street, Waterbury, Connecticut	06706	
Public Health Code Section #	Summary Statement of Violations	Corrective Actions/Responsibilities	Completion Date May 3, 2018

Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (2) and/or (d) Medical records (3) and/or (e) Nursing Services (1) and/or (i) General (6) and/or (f) Emergencies and/or (1) infection control. (1)	<p>1. Based on medical record reviews, review of facility documentation and interviews for two of three patients (Patients #7 and #9) admitted to the ED (emergency department), the facility failed to ensure that physician orders for IV (intravenous) fluid administration were followed.</p> <p>The finding incudes:</p> <p>a. Patient #7 received peritoneal dialysis for end stage renal disease and was admitted to the ED on 5/30/18 at 6:56 PM following a change in mental status and decreased oral intake. Nursing triage documentation at 7:02 PM indicated that the Patient's BP (blood pressure) was 98/50 (normal 120/70). Physician orders dated 5/30/18 at 7:29 PM directed an IV NS (normal saline) 1,000ml to run over 60 minutes via pump. IV documentation identified that the IV infusion was started by the nurse at 8:33 PM, was not completed within 1 hour and was completed on 5/31/18 at 12:15 AM (infusion time= 3.42 hours).</p> <p>The next set of vital signs were taken greater than 5 hours after the initial vital signs, were taken on 5/31/18 at 12:15 AM, the Patient's blood pressure had dropped to 67/54, MD #7 was notified and another IV of 1000 ml of NS was ordered to run over 60 minutes. IV documentation identified that the IV infusion was started by the nurse at 12:15 AM, was not completed within 1 hour and was completed on 5/31/18 at 2:24 AM (infusion time = 2.09 hours). The Patient's blood pressure dropped to 63/34 at 1:30 AM, 78/50 at 2:15 AM and an IV of 1000ml NS to run over 60 minutes was ordered by MD #11. IV documentation identified that the IV infusion was started by the nurse at 2:24 AM, was not completed within 1 hour and was completed on 5/31/18 at 6:19 AM (infusion time = 3.55 hours).</p> <p>Interview with Manager #1 on 5/3/18 at 10:43AM indicated that he did not know why the IV took so long to infuse as it was not documented. Interview with the ED Chief, MD #8, on 5/3/18 at 12:15 PM</p>	<p>Applies to 19-13-D3(b), 2(c), 2(d), 3(c), (1), (i), 6(f), (1).</p> <p>All ED Nursing staff to be educated on the requirement to document for the reason of the extended infusion IV time greater than the physician order for sepsis patients.</p> <p>All cases that do not meet documentation standard for IV infusion documentation to be reviewed at ED operations meeting which meets weekly.</p> <p>ED Nursing staff who do not meet IV infusion documentation to be remediated by ED manager.</p> <p>Monitoring: 10% of all sepsis patients to be audited for compliance for IV infusion documentation for 3 months.</p> <p>Responsible Person: Clinical Manager Emergency Operations</p>	<p>Completion Date. August 1, 2018</p> <p>October 11, 2018</p> <p>October 11, 2018</p>
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	<p>noted that the IVs should have been infused more timely and the nursing documentation did not indicate why the IV infused over a longer period of time.</p> <p>The facility RN job description directed to implement care regime according to standards of practice. The facility policy for standards of patient care identified that medications will be administered as prescribed.</p> <p>b. Patient #9 was admitted to the ED on 4/23/18 at 5:24 PM with flu-like symptoms.</p> <p>Nursing triage documentation at 5:27 PM indicated that the Patient's BP was 112/61 and temperature was 101.2 degrees Fahrenheit. Physician orders dated 4/23/18 at 6:38 PM directed an IV NS 1,000ml to run over 30 minutes.</p> <p>Review of the IV documentation and interview with the Director of Quality on 5/3/18 at 2:10 PM identified that the IV infusion was started by the nurse at 6:45 PM, was not completed within 30 minutes as ordered and was completed on 4/23/18 at 8:46 PM (infusion time = 2 hours).</p> <p>The facility RN job description directed to implement care regime according to standards of practice. The facility policy for standards of patient care identified that medications will be administered as prescribed.</p>		
<p>The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (2) and/or (1) General (6) and/or (4) Emergencies and/or (1)</p>	<p>2. Based on medical record reviews, review of facility documentation and interviews for one of three patients (Patients #7) admitted to the ED (emergency department) and who had an infection, the facility failed to ensure that orders by the physician were in accordance with the facility severe sepsis protocols, and/or that potential problems were addressed by the physician.</p> <p>The finding includes:</p> <p>a. Patient #7 received peritoneal dialysis for end stage renal disease and was admitted to the ED on 5/30/18 at 6:56 PM following a change in mental status and decreased oral intake. Vital sign records identified that the Patient's BP (blood pressure) was 98/50 (normal 120/70) at 7:02 PM and</p>	<p>Applies to 19-13-D3 (b), 2 (c), (i), 6 (i), (d), 1;</p> <p>Sepsis protocol developed which includes lactic acid lab orders to be completed stat and at 120 minutes when a patient's sepsis diagnosis is identified.</p> <p>Lab personnel educated to call ED physician directly for any lactic acid lab value greater than 2.</p> <p>Education for all physician and nurses regarding sepsis bundles which include ordering of lactic acids stat and at 120 minutes at point of patients' sepsis diagnosis. Education includes mandatory</p>	<p>July 1, 2017</p> <p>July 1, 2017</p> <p>March 1, 2017 & November 15, 2017</p>

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infection control (1).	<p>was 67/45 at 12:15 AM. Blood work ordered by MD #7 on 5/30/18 at 8:34 PM included, in part, a CBC (complete blood cell) count, liver function tests, and basal metabolic panel. The CBC resulted at 9:02 PM identified a high WBC (white blood cell) count of 18.8 k/uL (normal ^ 4.0-10.5) and MD #7 documented that he was aware of lab results at 10:50 PM. MD #7's documentation further noted that Patient #7 would be admitted under the Hospitalist and care would be dictated by MD #10. Physician documentation dated 5/30/18 at 10:55 PM indicated that because of the high possibility of imminent life/limb threatening deterioration in condition, the hospitalist was contacted. Nursing documentation dated 5/30/18 at 1:19 AM noted MD #10 went down to evaluate the Patient, BP remains low and the ICU Resident was called to the bedside. Although the Patient's WBC count was high, and BP remained low, a lactic acid (LA) level (high level could indicate sepsis) and/or blood cultures were not ordered. Interview with the Sepsis Coordinator (RN #5) and/or MD #8 on 5/31/18 at 10:55 AM and 12:15 PM respectively identified that it was known at 12:15 AM on 5/31/18 that the Patient was severely septic and a LA level and pan culturing should have been ordered at this time. MD #8 further indicated that although a LA level and blood cultures were not ordered, the Sepsis treatment protocol for the ordering of IV fluids and IV antibiotics was followed and the delay in bloodwork would not have altered the Patient's treatment.</p>	<p>attendance at noon conference, at ED nursing meetings, yearly mandatory on line education (e-learning) and at new hire orientation.</p> <p>Posters developed and distributed throughout the Emergency Department identifying Sepsis criteria including lactic acids.</p> <p>"Think SEPSIS" alert badge buddies distributed to ED staff for easy reference of Sepsis criteria.</p> <p>Physician and Nursing Best Practice Alerts (BPA) created as electronic reminders within EPIC that automatically trigger when 2 Sits criteria are met. BPA alert triggers again automatically in 4 hours to ensure Sepsis order set is utilized.</p> <p>All cases that do not meet standard for lactic acid protocol per criteria (stat and at 120 minutes) to be reviewed at ED operations meeting which meets weekly.</p> <p>Sepsis physician champion reviews all cases that fall out for non-timely lactic acids and remediates ED physicians directly.</p> <p>ED Physician Leadership also reviews sepsis cases that do not meet standard for ordering lactic acids and are brought to monthly ED physician meetings for review.</p> <p><u>Monitoring:</u> 10% of all sepsis patients to be audited for three months for compliance of ordering lactic acids per protocol.</p> <p><u>Responsible Person:</u> Clinical Manager ED Operations</p>	<p>March 2017</p> <p>February 2017</p> <p>May 1, 2018</p> <p>October 11, 2018</p> <p>October 11, 2018</p> <p>October 11, 2018</p> <p>October 11, 2018</p>

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Section 19-13-D3 (b) Administration (2) and/or (e) Nursing Services (1) and/or (i) General (6) and/or (j) Emergencies.	<p>4. Based on medical record reviews, review of facility documentation and interviews for one of three patients (Patients #7) admitted to the ED (emergency department) and who had an infection, the facility failed to ensure that a timely assessment of the Patient's vital signs was conducted.</p> <p>The finding includes:</p> <p>a. Patient #7 received peritoneal dialysis for end stage renal disease and was admitted to the ED on 5/30/18 at 6:56 PM, following a change in mental status and decreased oral intake. Nursing triage documentation at 7:02 PM indicated an ESI (emergency severity index) level "2" and a BP of (blood pressure) 98/50 (normal 120/70). Although the Patient's BP was not within normal range, a reassessment of the Patient's BP was not performed until 5/31/18 at 12:15 AM (5 hours later). The BP at this time was 67/54 and a second IV bolus of 1000ml of NS was ordered by MD #7 to infuse over 60 minutes.</p> <p>Interview with Manager #1 on 5/31/18 at 10:29 AM noted that the nurse should have reassessed vital signs every couple hours. The facility policy for emergency nursing assessment and reassessment of patients identified that those emergency patients with ESI scores of 1, 2, and 3 are reassessed with documentation of those reassessments at a minimum of every 2 hours.</p>	<p>Applies to 19-13-D3 (b), 2 (e), 1 (i), 6 (j): Installation of new computer system, EPIC completed. EPIC allows automated documentation of vitals and auto documents after nurses verify blood pressures.</p> <p>Monitoring: Will monitor 5 ED records for 4 weeks to ensure that vital signs are auto documenting in the patient record.</p> <p>Responsible Person: Clinical Manager of Emergency Operations</p>	<p>July 1, 2017</p> <p>August 3, 2018</p>	

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Section 19-13-D3 (c) Medical staff (3), and/or (e) Nursing service (2), (i) General (d).	6. Based on clinical record review, facility documentation and interviews for one of three sampled patients (Patient #2) who underwent a surgical procedure, the facility failed to monitor the intravenous site during a surgical procedure resulting in a significant infiltration of an extremity. The findings include: a. Patient #2 was admitted on 7/20/17 for a scheduled bilateral mastectomy with right sentinel node biopsy and bilateral breast reconstruction with DIEP flap procedure. The intravenous (IV) assessment sheet identified a peripheral 20 gauge IV was inserted into the left hand at 6:40AM. The IV assessment sheet identified peripheral 18 gauge IV was inserted into the left forearm at 7:55AM. Review of the intraoperative progress notes identified positioning of the patient included the left arm tucked at the patient's side with gel padding at the ulnar area and the right arm extended on an arm board with gel padding. Review of the IV assessment sheet identified that peripheral IV's were removed from the left hand and forearm in the OR at 6:00PM due to infiltration assessed 4+ edema. Review of the anesthesia record identified a total of 2500 ml Lactated Ringers was infused during the course of the procedure. Review of the operative note identified while changing the position of the patient to facilitate abdominal closure it was noted that the patient's left hand was swollen, pale and no palpable pulse. Further review identified that there had been difficulty with the IV infusion and that CRNA#1 had utilized a pressure bag to infuse the fluid because it was not running with gravity drainage. A blood pressure cuff was placed on the left upper arm. The note identified that both intravenous sites were infiltrated and that there were significant blistering along the forearm and elbow. Review of the orthopedic consultation progress note for date of service 7/20/17 indicated the reason for consult included IV infiltrate and concern for hand and forearm compartment syndrome. The progress note identified upon exam of the left upper extremity a palpable radial pulse was present and	Applies to 19-13-D3 (c), 3 (e), 2 (i), (d); Repositioning Policy updated to guide OR staff on repositioning a patient for breast reconstruction procedures with DIEP flap. The policy also details that pressure bags are no longer allowed on the arm that has a peripheral IV. OR Staff re-educated regarding Repositioning policy. Anesthesia met and identified alternative ways of IV access for extended breast flap procedures. The discussion included options for the patient to have IV access in the region of the foot, an option for the patient to come in prior to the procedure for a PICC line. Anesthesia staff re-educated on assessment requirements of peripheral IV's. <u>Monitoring:</u> Will monitor all of this provider's DIEP flap breast surgery for 3 months to ensure that Anesthesia staff has monitored peripheral IV access appropriately and that the positioning of the arm is documented per policy. Will observe all DIEP flap procedures by MD#1 for a period of one month to visualize that the correct positioning of the patient is occurring and that the peripheral IV is placed according to policy. <u>Responsible Person:</u> Director of OR Services	August 15, 2017 October 20 2017 October 20, 2017 October 20, 2017 December 31, 2017 August 9, 2018
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	<p>compartment pressure measurements were performed. Further review identified that compartment syndrome was not a concern, compartment release was not required, however, a recommendation of close observation of the left upper extremity, strict elevation and splinting. Review of the physician progress note dated 7/21/17 identified left upper extremity less swollen, good movement and blisters intact. The physician progress note dated 7/22/17 identified patient denies any complete paresthesia of left upper extremity, neurovascular intact and able to actively flex and extend all digits and wrist with no pain.</p> <p>Review of the discharge note dated 7/23/17 identified left arm with unroofed blisters, improved sensation to digit four and five, good capillary refill and range of motion and to continue with elevation of left upper extremity and daily wound care. Review of the facility investigation and documentation identified during this type of procedure no pressure bags with peripheral IV infusions and an alternative IV access should be considered i.e. central line, midline or PICC placement and file use of alternative devices for hemodynamic monitoring.</p> <p>Interview on 1/30/18 at 10:50AM with the Chief of Anesthesia (MD#1) identified he was not involved with Patient#1's surgery however, he identified positioning of a patient is a team effort and if an arm is tucked in anesthesia must ensure that the IV infusion is monitored. MD#1 further identified monitoring of the IV site should be done at a minimum once every hour or more if necessary, this would include anesthesia personnel checking under the sterile drapes to evaluate the extremity and if visualization is required communication with surgical team should be done.</p> <p>Interview on 1/30/18 at 2:00PM with the CRNA#1 identified she was assigned to Patient#2 and recalls there was a peripheral IV in the left forearm and that she inserted a second peripheral IV in the left arm. CRNA#1 identified a blood pressure cuff was placed above the IV sites on the left forearm and prior to surgical draping the IV infusions were running appropriately. CRNA#1 further identified prior to noon she noted the IV infusion was slowing, she informed</p>		
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	<p>the surgical team to be aware of their proximity to the patient's left side in addition to checking the IV tubing position. CRNA#1 did not visualize the arm, felt no obvious edema and the IV infusion appeared to be flowing. CRNA#1 stated about an hour later the IV infusion was slow and utilized a pressure bag to increase the flow. CRNA#1 identified at approximately 4:30PM the surgical team requested the O.R table to be flexed to reposition the patient and at this time she was able to visualize the left arm. CRNA#1 indicated the left arm had blisters, was edematous below the blood pressure cuff, no palpable radial pulse and fingers were purple. CRNA#1 identified the IV infusions were stopped, removed the blood pressure cuff while the surgical team assessed the arm. CRNA#1 identified positioning of the arm was done by the surgical team and that she was aware of the arm position. Interview on 1/31/18 at 10:25AM with the orthopedic physician (MD#2) identified he evaluated the patient's left arm while he/she was in the operating room. MD#2 identified the initial concern of compartment syndrome developing was not warranted because the compartment pressure measurements were within normal limits. MD#2 further identified blistering is very common with an IV infiltration and that the plan of care for Patient#2 included monitoring and elevation of the extremity. Review of the facility's patient positioning policy identified in part a preoperative assessment for positioning prior to surgery and that assessment includes type and length of procedure. The anesthesia provider monitors and maintains the physiological functioning of the patient and his/her requirements for anesthesia. Review of the short peripheral IV catheter insertion and maintenance policy identified in part frequency of peripheral IV site assessments for continuous IV drip to assess every two hours.</p>						

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Section 19-13-D3 (e) Nursing service, and/or (i) General and/or (i) Infection control.	<p>7. Based on clinical record review, facility documentation and interviews for one of three sampled patients (Patient #1) who were at risk for skin breakdown, the facility failed to ensure that care and services were provided to prevent a pressure ulcer developing.</p> <p>The findings include:</p> <p>a. Patient #1 was admitted on 8/22/17 status post fall at home with a diagnosis of right femur fracture. Patient #1's diagnoses include end stage renal disease (ESRD) on dialysis, chronic obstructive pulmonary disease (COPD) and atrial fibrillation. Review of the clinical record on 8/22/17 at 9:57 PM, identified that documentation of a head to toe nursing admission assessment was performed and the Braden scale risk assessment calculated a score of 17 (high risk). Review of the plan of care dated 8/22/17 at 11:39PM identified a problem of skin integrity with a goal to promote tissue integrity and outcome as progressing. Review of the brief operative note dated 8/24/17 identified that Patient #1 underwent open reduction internal fixation of right femur fracture. Review of the flowsheet shift assessment dated 8/24/17 at 11:00 AM identified prophylactic foam dressing applied to the sacrum and a Braden scale risk assessment score of 11. Review of the flowsheet shift assessment on 8/25/17 at 3:45 AM identified skin color ecchymosis, prophylactic foam dressing applied and a Braden scale risk assessment score of 14. The neurosurgical consult note dated 8/26/17 identified on 8/25/17, Patient#1 complained of inability to move his/her legs and decreased sensation.</p> <p>The assessment identified sudden onset of acute lower extremity paralysis. Review of the flowsheet shift assessment on 8/27/17 identified that the sacrum area was first assessed at 10:19pm and indicated that the patient had a pressure injury, large ecchymosis with small open areas. Further review identified that the wound was present on hospital admission and not hospital acquired. The assessment further described the pressure ulcer stage as</p>	<p>Applies to 19-13-D3 (e), (i), (l). OB4 staff educated on EPIC documentation for Daily Cares. Daily cares documentation is required every 2 hours.</p> <p><u>Monitoring:</u> Will audit 5 patient records a week for 4 weeks for patients with pressure ulcers that have had their daily care documentation completed every 2 hours.</p> <p><u>Responsible Person:</u> Clinical Nurse Manager O'Brien 4</p>	<p>July 18, 2018</p> <p>August 18, 2018</p>

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	<p>deep tissue injury (DTI), state of healing ecchymotic, wound bed maroon/purple, peri-wound skin clean dry intact, round shape measuring 7cm x 6cm with scant sanguineous drainage. Further review identified that the dressing was changed and replaced with a foam (Allevyn) dressing. The flowsheet shift assessment dated 8/28/17 at 1:00AM identified DTI(deep tissue injury) pressure ulcer, dressing clean, dry and intact, at 6:32AM identified DTI pressure ulcer, dressing changed, wound bed maroon/purple, no drainage, barrier cream applied and repositioned onto left side.</p> <p>Review of the wound care consult note dated 8/28/17 at 5:20PM identified DTI of the sacrum measuring 7cm x 12cm, no drainage, ecchymosis present and erythema. Review of the wound care orders directed to apply Allevyn sacral dressing, change every other day and a pressure redistributing low air loss mattress. Further review identified to follow up on discharge to evaluate how the wound progresses since the extent of the injury is unknown. Review of the flowsheet assessment dated 8/29/17 at 5:00PM identified dressing status clean, dry and intact. The flowsheet assessment dated 8/30/17 at 12:00PM identified patient repositioned every two hours and on 8/31/17 dressing assessed and changed. Review of the plan of care note dated 8/31/17 at 8:05 AM identified that Patient #1 was on a Cliniron (air fluidized mattress) bed. Review of the clinical record from 8/22/17 thru 8/31/17 failed to reflect consistent documentation of patient repositioning every two hours or other interventions used for pressure ulcer prevention. Review of the wound care consult note dated 8/31/17 at 2:30PM identified sacrum with large DTI, unchanged and potential for area to turn into an unstageable ulcer which will need debridement. Review of the discharge summary dated 8/31/17 identified Patient #1 continued to have bilateral lower extremity flaccid paralysis and numbness, the patient was transferred to another facility for higher level of care on 8/31/17.</p> <p>Interview on 1/29/18 at 2:00PM with the Unit Nurse Manager (RN#3) failed to provide documentation that the patient was</p>			

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	<p>turned and/or repositioned every two hours. RN#3 indicated that all mattresses at the facility are deemed air pressure relieving and that staff do not document when a patient is repositioned every two hours because it is standard of care. RN#3 further identified that during change of shift nursing staff will communicate when the patient requires repositioning.</p> <p>Review of the facility's procedure documentation for pressure injury prevention identifies in part that a DTI results from prolonged pressure, treatment includes methods to decrease pressure and to turn and reposition the patient every 1 to 2 hours or more frequently as required.</p>						

